

AUG 25 1997

Ms. De Lois L. Shelton
Regulatory Compliance
Weider Nutrition Group, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

0015 '97 SEP 19 P1:26

Dear Ms. Shelton:

This is in response to your letter of August 12, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for the product "Pain Free," distributed by Great American Nutrition:

PAIN FREE from Great American Nutrition is an all natural way to ease joint aches...without the use of harsh chemicals. PAIN FREE contains Glucosamine which is fully metabolized when taken orally, is used in the body to manufacture cartilage components necessary for joint repair. Glucosamine comprises 50% of hyaluronic acid, a main ingredient of synovial fluid, a lubricant for all the joints.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggest that it is intended to treat or mitigate a disease, in that the name "PAIN FREE" and the statement "ease joint aches" evidence that it is intended to treat or mitigate pain. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Los Angeles District Office, Office of Compliance, HFR-SW240

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200